CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III.

Manufacturer: Anbio (Xiamen) Biotechnology Co.,Ltd.
Address: No.2016, Wengjiao West Road, Xinyang Street, Haicang District,361026 Xiamen, Fujian, China.

European Representative: Lotus NL B.V.

Contact person: Peter **E-mail**: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague, Netherlands.

In Vitro Diagnostic Directive:

- **Rapid COVID-19 Antigen Test (Colloidal Gold)**

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:04/09/2020

Place:Xiamen,China

Name of authorized signatory: Danny Wang
Position held in the company: General Manager
Seal/Stamp:

Anbio (Xiamen) Biotechnology Co.,Ltd.

Bestätigung vom PEI evaluierte Test

Sehr geehrte Damen und Herren,
Wir, Anbio (Xiamen) Biotechnology Co. Ltd. No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen, Fujian, China bestätigen hiermit, dass der vom Paul-Ehrlich-Institut evaluierte Test analytisch identisch mit dem antragsgegenständigen Test ist.

Mit freundlichen Grüßen,

Daming Wang
CEO von Anbio Xiamen Biotechnology Co. Ltd
Xiamen, 07 Mar 2021

BUREAU VERITAS
Certification

Anbio (Xiamen) Biotechnology Co., Ltd

No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen City, P.R. China

Certified site:

NO.2016, WENGJIAO WEST ROAD, XINYANG STREET, HAICANG DISTRICT, XIAMEN CITY, P.R. CHINA

Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

EN ISO 13485:2016

Scope of certification

Design and manufacture of fluorescence-based immunoassay reagent and devices, as an aid in clinical assessment of cardiovascular, gastric, inflammation, diabetic and infectious diseases detection, as well as hormone, vitamin testing. Design and manufacture of IVD reagents as an aid in clinical assessment of blood type testing.

Certificate awarded in conformity with the requirements of ACCREDIA DT 02-DC Rev.00

Original cycle start date:	**22/06/2020**
Expiry date of previous cycle:	**n.a.**
Certification / Recertification Audit date:	**17/05/2020**
Certification / Recertification cycle start date:	**22/06/2020**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **21/06/2023**

Certificate No. - Version: IT298645-1 Revision date: **22/06/2020**

GIORGIO LANZAFAME – *Local Technical Manager*

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 009A

Member of Mutual Recognition EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it